

## **DETAILED ACTION**

### ***Amendment***

1. This office action is responsive to the amendment filed on 7/6/10. As directed by the amendment: claims 1 and 2 have been amended, no claims have been canceled, and no new claims have been added. Thus, claims 1-3 are presently pending in the application.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, lines 11-12 recites "wherein only when the inhaler aid is joined to a mouthpiece of the inhaler for the minute powdery curative medicine and an inhalation has been correctly performed, a sound is produced from the reed". However, it appears that applicant's reed would still create a noise regardless of whether the aid was joined with the mouthpiece if a certain flow rate was produced. Clarification is required.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinkade (5,062,422) in view of Steiner (2004/0182387), Foley (5,042,467) and MacRae et al. (2002/0046751).

Regarding claim 1, in fig. 7 Kinkade discloses a main unit 12 having a resilient material (Col. 2, ll. 12-13) tube (where 12 is pointing in fig. 1, tube passageway can be seen in fig. 8) used to aid an inhaler (Col. 1, ll. 10-13), and a horn-shaped junction 6 at a lower portion of the main unit; an engagement portion (where 10 is pointing in fig. 1) which is provided at an upper portion of the main unit, the engagement portion including and constituted of left and right projections, each having a holding member 2 at an end thereof. Kinkade is silent regarding a reed that produces a sound when an inhalation

has been correctly performed. However, Steiner teaches an inhaler with a reed located within the air-flow path that produces an audible signal when operating the inhaler correctly (proper airflow has been established, Page 4, para 60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's inhaler with a reed, as taught by Steiner, for the purpose of assuring the patient of proper use and enhancing inhalation therapy. The modified Kinkade discloses a reed indicating that an inhalation has been correctly performed, but is silent regarding that the reed is located on the main unit and produces the sound when the inhaler aid is joined to the mouthpiece. However, Foley teaches a reed 90 located on a main unit 14 that produces a sound when connected with the mouthpiece. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kinkade's main unit with the reed and noise production when the aid is connected to the mouthpiece, as taught by Foley, for the purpose of assuring the patient of proper use when the device is properly assembled and producing less interference with the medicament upon inhalation. The modified Kinkade is silent regarding that the reed is located on the right side of the main unit, however the specific location of the reed being on the right side of the main unit appears to be an obvious design consideration as it appears that the reed would perform equally as well located at any location on the circumference of the main unit. The modified Kinkade is silent regarding that the main unit is made from a silicon rubber. However, MacRae teaches an adapter body made from synthetic rubber, and preferably of a silicone material (Page 5, para 111). Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to modify Kinkade's main unit with a silicone rubber material, as taught by MacRae, for the purpose of providing a flexible and comfortable mouthpiece.

Regarding claim 2, the modified Kinkade of claim 1 discloses the claimed invention, but is silent regarding a powder medicament. However, MacRae teaches a powder medicament (page 6, para 115). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's main unit with a powder medicament, as taught by MacRae, for the purpose of providing different types of medication and therapies to a user.

Regarding claim 3, the modified Kinkade of claim 1 discloses the claimed invention.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new grounds of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kistler (4,291,688) to an inhaler with a reed that produces sound only when an inhalation is being performed correctly. Any inquiry concerning this communication or earlier communications from the examiner should be directed to

RACHEL YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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